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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,786

04/16/2004

Tracee E.J. Eidenschink

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CROMPTON, SEAGER & TUFTE, LLC  
1221 NICOLLET AVENUE  
SUITE 800  
MINNEAPOLIS, MN 55403-2420

EXAMINER

MATNEY, BROOKE MARIE

ART UNIT

PAPER NUMBER

3763

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,786	<b>Applicant(s)</b> EIDENSCHINK ET AL.	
	<b>Examiner</b> Brooke M. Matney	<b>Art Unit</b> 3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/27/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. This office action is responsive to the preliminary amendment filed on 4/16/2004. As directed by the amendment: claims 1-27 have been canceled, and new claims 28-39 have been added. Thus, claims 28-39 are presently pending in the application.

### ***Claim Objections***

2. Claims 33 and 34 are objected to because of the following informalities: Claim 34 is a duplicate of claim 33. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 28-35, 38, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by *Windheuser et al.* [U.S. Patent No. 6,096,009].

As to claim 28, *Windheuser et al.* discloses a medical device comprising: a catheter (350, Fig. 11), the catheter defining at least one wire lumen (60, Fig. 1B) for passage of a first wire (36) therethrough, and a second wire therethrough (cutting wire, Col. 6, ll. 6-9), the catheter having a proximal end region and a distal end region, the proximal end region comprising a manifold (the proximal

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region of 350 where the locking device attaches, Fig. 11), the manifold defining at least one port (354, Fig. 12), the at least one port being in communication with the at least one wire lumen (Fig. 12); a wire station (locking device having body member 360, Fig. 12), the wire station system comprising a base platform (360) and a manifold engagement mechanism (hook members 358, Fig. 11), the manifold engagement mechanism constructed and arranged to removably engage the base platform to an engagement region of the manifold (Fig. 11), the base platform having a wire management system (Fig. 12), the wire management system being actuatable between a first and a second position, in the first position each wire being moveable along a longitudinal axis, in the second position at least one the wires being fixedly engaged to the wire management system (Col. 15, ll. 27-35). The parts of the locking member around the guide wire opening 362 can be moved relative to the guidewire from the first position to the second position, and are therefore actuatable between the positions.

As to claim 29, *Windheuser et al.* discloses wherein the catheter is a bifurcated catheter (Fig. 11).

As to claim 30, *Windheuser et al.* discloses wherein the catheter defines a first wire lumen and a second wire lumen separate from the first wire lumen (Fig. 1B).

As to claim 31, *Windheuser et al.* discloses wherein the manifold comprises a plurality of ports (354 and the port at the proximal end of main shaft 352, Fig. 11), at least one of the ports being in communication with the first wire

lumen and the second wire lumen (354 is in communication with the first wire lumen and second wire lumen, Fig. 12).

As to claim 32, *Windheuser et al.* discloses wherein the wire management system comprises a first wire securement mechanism (J-shaped guide wire opening 362, Fig. 12 or opening 410, Fig. 14) and a second wire securement mechanism (opening 370, Fig. 12, or flap-type opening 412, Fig. 14, Col. 16, ll. 18-32), each securement mechanism being independently actuatable between the first position and the second position.

As to claims 33 and 34, *Windheuser et al.* discloses wherein each securement mechanism is a clothespin-type securement mechanism (opening 410 and flap 414, Fig. 14, Col. 16, ll. 18-32). Examiner is interpreting clothespin-type securement mechanism to be a securement mechanism where two sides of the mechanism apply a force to hold the guidewire. The opening 410 is J-shaped to allow the guidewire to be moved into the locking slot and be frictionally engaged between the two sides of the slot applying force on the guidewire. The flap provides force between the guide wire and the body member to effectively secure the guide wire to the body member.

As to claim 35, *Windheuser et al.* discloses wherein each securement mechanism is a cullet-type securement mechanism (opening 410 and flap 414, Fig. 14, Col. 16, ll. 18-32). Examiner is interpreting cullet-type securement mechanism to mean a securement mechanism where force is applied from both sides of a body that is split around the wire being secured. The opening 410 is J-

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shaped to allow the guidewire to be moved into the locking slot and be frictionally engaged between the two sides of the slot applying force on the guidewire. The flap provides force between the guide wire and the body member to effectively secure the guide wire to the body member.

As to claim 38, *Windheuser et al.* discloses wherein each securement mechanism is a partial slit wire securement mechanism (opening 410 and flap 414, Fig. 14, Col. 16, ll. 18-32). The opening 410 is J-shaped to allow the guidewire to be moved into the locking slot and be frictionally engaged between the two sides of the slot applying force on the guidewire. The flap provides force between the guide wire and the body member to effectively secure the guide wire to the body member in the slit between the flap and the body member.

As to claim 39, *Windheuser et al.* discloses wherein at least one of the first wire and second wire is a guidewire (366).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Windheuser et al.* [U.S. Patent No. 6,096,009] in view of *Chin et al.* [U.S. Patent No. 6,796,976 B1].

As to claims 36 and 37, *Windheuser et al.* discloses all of the limitations of claim 32. *Windheuser et al.* does not disclose wherein each securement mechanism is a magnetic wire securement mechanism or a cam-type wire securement mechanism.

*Chin et al.* teaches fasteners for securing a guidewire that can be a magnetic wire securement mechanism (magnets, Col. 6, ll. 19-29) or a cam-type wire securement mechanism (locking devices and latches, Col. 6, ll. 19-29).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify *Windheuser et al.*'s medical device so that it uses either a magnetic wire securement mechanism or a cam-type wire securement mechanism, as taught by *Chin et al.*, because these types are known in the art to securely hold a guidewire and restrict the guidewire's movement during a surgical procedure. Using a magnetic wire securement mechanism simplifies the design of the medical device and using a cam-type securement mechanism allows for secured locking ability and control.

***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 28 is rejected on the ground of nonstatutory double patenting over claims 1-3 of U. S. Patent No. 6,746,466 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Both the patent and the instant application claim two wire members, a catheter, a wire management system having a first position where the wires are movable along an axis and second position where the wires are fixedly engaged to the wire management system, a base platform, a clasp portion (manifold engagement mechanism in instant application), and a manifold port.



Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brooke M. Matney whose telephone number is (571)270-1457. The examiner can normally be reached on Monday-Thursday 9AM-7PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brooke M Matney/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art  
Unit 3763